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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,284

11/15/2006

John Erwin Farley

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04/03/2009

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EXAMINER

GRASER, JENNIFER E

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,284	<b>Applicant(s)</b> FARLEY ET AL.	
	<b>Examiner</b> Jennifer E. Graser	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-102 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-23, 25-39, drawn to a method of increasing the expression levels of a Neisseria PorA protein or polypeptide in a host cell. NOTE: If this Group is elected, Applicant must also elect a single polynucleotide which is to be used in the method for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

Group II, claim(s) 24, 40-43, drawn to an isolated porA protein or polypeptide and compositions comprising said polypeptides. NOTE: If this Group is elected, Applicant must also elect a single polypeptide for examination, e.g., SEQ ID NO: X. This is a Restriction Requirement, not a species election.

Group III, claim(s) 44, drawn to a method for identifying Neisseria polynucleotides encoding porA proteins/polypeptides which are expressed at low levels in a host cell by obtaining a mature Neisseria polynucleotide sequence, determining the triplet sequence at codon 17 sequence.....

Group IV, claim(s) 45-47, drawn to an isolated polynucleotide. NOTE: must specify SEQ ID NO.. NOTE: If this Group is elected, Applicant must also elect a single polynucleotide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

Group V, claim(s) 48, drawn to a a method for identifying Neisseria polynucleotides encoding porA proteins/polypeptides which are expressed at low levels in a host cell by obtaining an endogenous Neisseria polynucleotide sequence, determining the 5' signal sequence, hypothetically deleting the 5' signal sequence.....

Group VI, claim(s) 49-51, drawn to an isolated polynucleotide. NOTE: If this Group is elected, Applicant must also elect a single polynucleotide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

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Group VII, claim(s) 52-53, 55 and 56, drawn to a method for increasing the expression levels of a *Neisseria porA* polypeptide or protein comprising obtaining a mature *Neisseria* polypeptide sequence, determining the triplet sequence at codon 17 and replacing it with a codon other than ATC.

Group VIII, claim(s) 54, 59 and 60, drawn to an isolated polynucleotide. NOTE: If this Group is elected, Applicant must also elect a single polynucleotide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

Group IX, claim(s) 61, 62, 64 and 65, drawn to a method for increasing the expression levels of a *Neisseria porA* proteins/polypeptides which are expressed at low levels in a host cell by obtaining an endogenous *Neisseria* polynucleotide sequence, determining the 5' signal sequence, hypothetically deleting the 5' signal sequence, determining the triplet codon sequence at at codon 17 and replacing it with a codon other than ATC.

Group X, claim(s) 63, ,68 and 69, drawn to an isolated polynucleotide. NOTE: If this Group is elected, Applicant must also elect a single polynucleotide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

Group XI, claim (s) 70 and 71, 73 and 74, a method for tincreasing the expression levels of a *Neisseria porA* proteins/polypeptides in which involves selecting an alternative *Neisseria* strain wherein codon 17.

Group XII, claim(s) 72, 77 and 78 drawn to an isolated polynucleotide. NOTE: must specify SEQ ID NO.. NOTE: If this Group is elected, Applicant must also elect a single polynucleotide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

Group XIII, claim(s) 75 and 76, drawn to an isolated polypeptide. NOTE: must specify SEQ ID NO.. NOTE: If this Group is elected, Applicant must also elect a single polypeptide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

Group XIV, claim(s) 79, 80, 82 and 83, drawn to another method of increasing the expression levels of a *Neisseria PorA* protien or polypeptide which involves the hypothetical deletion of the 5' signal sequence and that involves the selection of an alternative *Neisseria* strain.

Group XV, claim(s) 81, 86 and 87 drawn to an isolated polynucleotide. NOTE: must specify SEQ ID NO.. NOTE: If this Group is elected, Applicant must also elect a single polynucleotide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

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Group XVI claim(s) 84 and 85, drawn to an isolated polypeptide. NOTE: must specify SEQ ID NO.. NOTE: If this Group is elected, Applicant must also elect a single polypeptide for examination, e.g., SEQ ID NO: 1. This is a Restriction Requirement, not a species election.

Group 17, claim(s) 88 and 89 drawn to a method of immunization using SEQ ID NO:2.

Group 18, claim(s) 90 and 91 drawn to a method of immunization using SEQ ID NO:4.

Group 19, claim(s) 92 and 93 drawn to a method of immunization using SEQ ID NO:14

Group 20, claim(s) 94 and 95 drawn to a method of immunization using SEQ ID NO:16.

Group 21, claim(s) 96 and 97 drawn to a method of immunization using SEQ ID NO:25.

Group 22, claim(s) 98-101, drawn to a method of immunization with a multivalent composition comprising SEQ ID Nos., 2, 4, 14, 16, 25 or fragments thereof.

Group 23, claim 102, drawn to an immunogenic composition. NOTE: IF this Group is elected, Applicants must elect a single composition by SEQ ID NO.; e.g., a composition comprising SEQ ID NO: 2 and SEQ ID NO: 6; a composition comprising SEQ ID NO: 14 and 10, etc. This is a Restriction Requirement, not a species election as this group contains numerous independent inventions.

2. The inventions listed as Groups I-23 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The Inventions of Groups I-23 do not contain the same special technical feature as they contain completely separate methods and/or products which are biologically, structurally and chemically distinct products. Additionally, there are patentably distinct products contained **within** many of these three groups, e.g., nucleotide sequences encoding different proteins (as well as proteins comprising different amino acid sequences/encoded by different nucleic acid sequences) are structurally distinct chemical compounds and are different special technical features. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a species election requirement.

The polypeptide of groups 2, 13 and 16 and the polynucleotides of groups 4, 6, 8, 10, 12 and 15 represent different special technical features for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. Furthermore, searching the inventions of groups 2, 13 and 16 and 4, 6, 8, 10, 12 and 15 together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. There is search burden also

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in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions together.

Inventions in Groups 1, 3, 5, 7, 9, 11, 14, and 17-22 are unrelated as they comprise different special technical features. The methods are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. The instant specification does not disclose that these methods would be used together. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis/identification/immunization differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons the Inventions of Groups 1, 3, 5, 7, 9, 11, 14, and 17-22 comprise different special technical features. Furthermore, the distinct steps and products require separate and distinct searches.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

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claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/  
Primary Examiner, Art Unit 1645

3/30/09